IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES LIMITED and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant	**PUBLIC VERSION** Civil Action No. 05-197-GMS

PLAINTIFF GLAXOSMITHKLINE'S RESPONSE TO DEFENDANT'S MOTION *IN LIMINE* NO. 2 TO EXCLUDE EXPERT TESTIMONY BY PATENT ATTORNEY EGON BERG

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GlaxoSmithKline ("GSK") submits this memorandum in opposition to Teva's motion *in limine* No. 2 requesting an Order precluding the expert report and testimony of Mr. Egon Berg from being presented at trial. Teva has asserted unprecedented inequitable conduct claims that seek to label as fraudulent routine patent prosecution practice in the chemical and pharmaceutical arts. Mr. Berg has over 47 years of experience as a patent attorney and examiner and was the chief patent counsel of Wyeth, a large pharmaceutical company. His testimony would assist the Court in evaluating Teva's claims by providing important context concerning how chemical and pharmaceutical inventions are claimed and protected. His testimony should therefore be allowed.

I. Introduction

Teva asserts that the inventors of the patents in suit committed inequitable conduct by claiming their inventions in genus claims even though they only reduced to practice a single species within that genus; namely, the drug ropinirole hydrochloride and its use for the purpose of treating Parkinson's Disease.

Inventors commonly do, and must, claim more broadly than the specific embodiments that they reduce to practice. Such claims are referred to as "genus" or "generic" claims that cover not only the specific embodiment that an inventor may have reduced to practice but a broader invention that fairly reflects the inventor's contribution to the art.

In this case, one of the asserted patents, U.S. Patent No. 4,452,808 ("the '808 patent"), is directed to chemical compounds and pharmaceutical compositions comprising them. The inventor, Gregory Gallagher, was the first to discover ropinirole hydrochloride, and his patent application describes that compound and related compounds and how to make them. Dr. David Owen was the first to discover that ropinirole hydrochloride could be used to treat Parkinson's Disease. He received U.S. Patent No. 4,824,860 ("the '860 patent") based on his invention.

Both patents include genus claims directed to a genus of chemical compounds that is broader than ropinirole hydrochloride itself. It was plain on the face of the applications what work the inventors did and did not do. The Patent Office allowed genus claims in both patents because the discovery of ropinirole hydrochloride and its use to treat Parkinson's Disease entitled the inventors to claim subject matter of suitable scope to protect the inventions disclosed in the patents.

None of the genus claims is asserted in this case, so whether such claims are enabled or adequately described under 35 U.S.C. §112 is not an issue in the case. Nonetheless, Teva claims

that the '808 and '860 patents are unenforceable based on the contention that it was inequitable conduct to even seek genus claims. Mr. Berg's expert report is primarily directed to this defense.

In particular, Mr. Berg describes standard practices in the pharmaceutical industry for how pharmaceutical inventions are claimed and analyzes the generic claims of the '808 and '860 patents in light of those practices. (Expert Report of Egon Berg ¶¶26-38 ("Berg Report"), attached as Exhibit A to the Affidavit of Cristina C. Ashworth, attached hereto as Exhibit 1.) Teva contends that a misrepresentation occurred with respect to inventorship of the patents and will, no doubt, argue that an intent to deceive the Patent Office should be inferred. Mr. Berg's testimony will, among other things, directly rebut any such inference by demonstrating that the conduct of the inventors was entirely consistent with normal patent prosecution practice at the time the patents were being considered by the Patent Office.

Mr. Berg's report also addresses a second inequitable conduct claim of Teva concerning whether the '808 patent provides misleading information concerning human dosage amounts. According to Teva, the '808 patent suggests that ropinirole had been tested for an effective dose in humans. In connection with this argument, Mr. Berg explains the differences between prophetic and working examples in patent applications and describes the practice in this art with regard to when compound claims would be sought in relation to the timing of human clinical trials. Berg Report ¶¶ 39-42 (Ashworth Affidavit, Ex. A.) This testimony will demonstrate that there was no misrepresentation and that a patent examiner would have understood that the discussion of dosage amounts in the '808 patent was purely prophetic and not representative of actual human testing.

II. Argument

Mr. Berg's report and testimony at trial is relevant and will assist this Court in understanding the evidence in this case. Specifically, Mr. Berg will assist the Court in understanding how chemical genus claims are prosecuted and examined before the United States Patent and Trademark Office. His testimony will assist the Court's evaluation of both materiality and intent. Further, the reasonableness of the genus claims sought in the asserted patents requires a comparison of different classes of chemical compounds disclosed in both the asserted patents and a prior art GSK patent. As a patent lawyer with a technical background in chemistry, Mr. Berg is uniquely suited to explain to the Court the relationship between the various compounds and classes of compounds that are described in the asserted patents and the prior art.

Thus, Mr. Berg is testifying as an expert on matters of which the Court may not otherwise be aware, notwithstanding its experience with patent cases. The subject matter of his testimony is not addressed by the case law or the testimony of the fact witnesses in the case. For example, Mr. Berg's report addresses the following questions, which are not covered by any other sources available to the Court: What is the routine practice for patent attorneys and examiners when dealing with generic claims made during patent prosecution related to chemical compounds? How are prophetic examples construed when examined by a USPTO examiner, and what would the specific example alleged by Teva to be "misleading" have been ordinarily understood to mean by the USPTO under standard practice? What would persons skilled in the art, including patent examiners, know about human dosage information and its relationship to clinical trials? How are claims drafted in a pharmaceutical company, and who is responsible for determining the scope of the claims that will be presented? What is the role of the patent attorney during the

prosecution of such chemical claims as those at issue in this case? Why are (often broad) chemical genus claims a necessary and routine part of patent prosecution? What is the relationship of the specific compounds and classes of compounds disclosed in the asserted patents and the prior art, and how do these disclosures relate to the class of compounds claimed in the generic claims? *See* Berg Report (Ashworth Affidavit, Ex. A.)

Mr. Berg's opinions are based upon his 47 years of experience as a patent attorney and examiner. The legal citations in his report provide the legal foundation for the standards and practices before the USPTO, but Mr. Berg is not purporting to express an opinion concerning, for example, whether the generic claims are enabled or adequately described under 35 U.S.C. §112. There is no Section 112 issue in this case because the generic claims are not even asserted against Teva. Rather, Mr. Berg is opining that the generic claims reflect claims of reasonable scope of the sort that would customarily be presented in a pharmaceutical patent. Such testimony is directly relevant to Teva's charge of inequitable conduct.

An examination of Mr. Berg's report, in contrast to Teva's characterization of it, demonstrates the inapplicability of the case law on which Teva relies. Mr. Berg is not "explaining patent law" as was the issue in *W.R. Grace & Co. v. Vikase Corp.*, 1991 WL 2611647, at *1 (N.D. Ill Oct. 15, 1991). Rather, he is explaining how the patent case law is routinely put into practice in everyday prosecution before the USPTO, from which the reasonableness of GSK's conduct can be judged.

Teva's reliance on *Applied Materials, Inc. v. ASM*, 2004 WL 2106583, *1 n.1 (D. Del. Sept. 8, 2004) is also misplaced. In that case, the court granted Applied Materials' motion to exclude the testimony of a former patent examiner because he was prepared to testify how he *personally* would have reacted had *he* been the examiner, and because he was not skilled in the

relevant art. In this case, Mr. Berg is not testifying how he personally would have reacted in the examiner's place. Furthermore, Mr. Berg is skilled in the chemical arts and has the technical background necessary to examine chemical claims. He has an academic background in chemistry, and experience prosecuting chemical arts patents as an attorney, and he formerly held a position as chief patent counsel at Wyeth, a large pharmaceutical company.

Teva's reliance on *Ondeo Nalco Co. v. Eka Chem., Inc.*, 2003 WL 1524658 (D. Del. Mar. 21, 2003) is similarly misplaced. In that case, the court ruled that the expert report exceeded the permissible scope of expert testimony because the patent attorney's report speculated about how the USPTO *would* have reacted to a set of hypothetical facts that did not occur. By contrast, Mr. Berg's report does not speculate about hypothetical facts, but provides the court with an understanding of how the *actual* facts fit within USPTO guidelines for examination of chemical patent applications.

The proposed testimony of Mr. Berg contrasts markedly with that of the expert witness in *Revlon Consumer Products v. L'Oreal S.A.*, 1997 WL 158281 at *2-3 (D. Del. Mar. 26, 1997). In *Revlon*, the expert proffered testimony on many substantive areas of patent law, including novelty, utility, and nonobviousness under §§101, 102, 103, and specification requirements under §112. Unlike the legal analysis in that case, Mr. Berg's report does not reference any specific section of U.S.C. Title 35 apart from a single mention of §112 in a parenthetical cite in footnote 2 (Berg Report at 16, n.2). Rather, the report is meant to provide the court with factual testimony related to how prosecution of the claims at issue was within the standard practice of both patent attorneys and USPTO examiners when prosecuting applications in the chemical arts.

Teva further cites the court's order in *Syngenta Seeds, Inc. v. Monsanto Co.*, 2004 WL 2106583, *1 n.1 (D. Del. Sept. 8, 2004) excluding the use of expert witnesses on patent law and

procedure. The court in *Syngenta* specifically pointed out that patent office practice and procedure were to be explained by the court to the jury in the form of an instructional video presentation, and that further testimony by expert witnesses covering similar ground was not necessary and therefore excluded. Here, Mr. Berg is offering specific testimony relating to the prosecution of chemical genus claims, and there is no alternative source of this information that would render Berg's testimony unnecessary.

III. Conclusion

Teva's Motion *in limine* 2 should be denied.

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Dated: October 30, 2006

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PROPOSED ORDER DENYING TEVA'S MOTION *IN LIMINE* NO. 2

The Court, having considered Defendant Teva's Pharmaceuticals USA Inc.'s ("Teva") Motion *In Limine* No. 2 to Exclude Expert Testimony By Patent Attorney Egon Berg and the response of Plaintiff Smith Kline & French Laboratories Limited and SmithKline Beecham Corp, d/b/a/ GlaxoSmithKline ("GSK"), and all further arguments by the parties, hereby ORDERS this _____ day of _____, 2006 that Teva's Motion is DENIED.

_____

United States District Judge

CERTIFICATE OF SERVICE

I, Patricia Smink Rogowski, hereby certify that on November 6, 2006 **Public Version of Plaintiff GlaxoSmithKline's Response to Defendant's Motion In Limine No. 2 To Exclude Expert Testimony by Patent Attorney Egon Berg** was filed with the Court Clerk using CM/ECF which will send notification of such filing(s) to Josy W. Ingersoll.

I hereby further certify that on November 6, 2006, I have also served this document on the attorneys of record at the following addresses as indicated:

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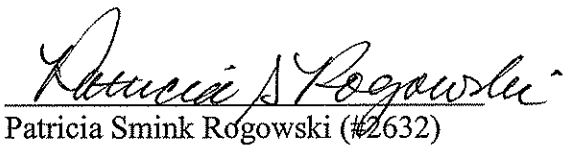

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